SENSITIVITY AND SPECIFICITY TEST REPORTS
2019-nCoV IgG/IgM Rapid Test Cassette (1-360-K025)

METHOD

Accelerated Stability of the 2019-nCoV IgG/IgM Rapid Test Cassette was compared with acommercial PCR; the results show that 2019-nCoV IgG/IgM Rapid Test Cassette has a high sensitivity and specificity.

Table: Sample Correction Result

Performance of IgG Specimen

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test	Results	**Positive**	**Negative**	
	Positive	20	1	21
	Negative	0	49	49
Total Result		20	50	70

Relative Sensitivity: 100% (95%CI*: 86.0%-100%)   *Confidence Interval

Relative Specificity: 98.0% (95%CI*: 89.4%-99.9%)

Accuracy: 98.6% (95%CI*: 92.3%-99.96%)

Performance of IgM Specimen

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test	Results	**Positive**	**Negative**	
	Positive	17	2	19
	Negative	3	48	51
Total Result		20	50	70

Relative Sensitivity: 85.0% (95%CI*: 62.1%-96.8%)   *Confidence Interval

Relative Specificity: 96.0% (95%CI*: 86.3%-99.5%)

Accuracy: 92.9% (95%CI*: 84.1%-97.6%)

CONCLUSION

The 2019-nCov IgG/IgM Rapid Test Cassette products have been compared with a commercial PCR using clinical specimen. The results show that the relative sensitivity of the 2019-nCov IgG/IgM Rapid Test Cassette is 100% for IgG and 85% for IgM. The relative specificity is 98.0% for IgG and 96.0% for IgM.